

REMARKS

Claims 1-30 were rejected as anticipated by U.S. Patent No. 5,383,472 (Devlin et al.) "Devlin". This rejection is respectfully traversed. Claim 1 describes an image of the tissue specimen suitable for pathological examination, whereas Devlin's container is only for providing radiological images (see Abstract and FIGS. 6A-6B). Radiology and pathology are different medical specialties. Radiology is the transmittance of high energy x-rays to provide image on film which are shadows through a specimen. In contrast, pathology deals with analysis of cellular and/or structure organization of tissue, and as such requires the capability of imaging at microscopic resolutions. Devlin supports this at column 6, lines 28-57, and column 7, lines 9-34, where the container 16 is radiologically imaged, and then the film x-ray image and the specimen 14a in the container are sent to pathology with the coordinates of the lesion, and only then does the pathologist extract the suspect tissue from the specimen to make a diagnosis of the suspect tissue. Clearly, Devlin itself shows that his x-ray analysis is not comparable to pathological examination, for if it were, he would not have stated that such tissue after x-ray imaging requires pathological examination to make a diagnosis. Accordingly, Devlin fails to disclose any image suitable for pathological application. An x-ray image may provide a location of suspect tissue in a specimen, but that suspect tissue still requires pathology. Also, Devlin fails to disclose the scanning means of Claim 1 for providing such an image suitable for pathological application. X-ray imaging cannot represent the scanning means where a radiograph would not be an image suitable for pathological application, otherwise, why would Devlin state that pathological examination is performed after completion of the x-ray. Clearly, Devlin fails to disclose each and every element of Claim 1, and withdrawal of the rejection is requested. Further, Claim 15 depends on base Claim 1, and thus not anticipated by Devlin.

Claims 2 and 5 also cannot be anticipated by Devlin where Devlin does not disclose a confocal imaging system. Devlin discloses only radiological imaging of its container, and radiological imaging is not the same, or even comparable, to confocal imaging. For example, confocal imaging can produce images which are microscopic in resolution, while radiological imaging cannot. Thus, Claims 2 and 5 cannot be anticipated by Devlin.

Claims 3, 4, and 6 describe a stage which may be used with the holder of Claim 1 for moving the holder. Devlin's figures show a container without any stage. Moreover, no stage is even suggested where Devlin describes that the specimen in its container can

be compressed in an x-ray machine while an x-ray image is taken (see column 6, lines 34-37, and column 7, lines 12-14). Thus, Claims 3, 4 and 6 cannot be anticipated by Devlin.

Claim 7 further describes the holder of Claim 1 as a trocar. No figures or description in Devlin shows its container as being a trocar to support anticipation of Claim 7.

Claims 8-12, and 30 describe the holder of Claim 1 as a shell and the scanning means of Claim 1 as further comprising means for rotating the shell and means for translating the shell. No such rotating means or translating means is disclosed anywhere in Devlin. Moreover, no rotating means or translating means is needed since the specimen in its container can be compressed in an x-ray machine while an x-ray image is taken (see column 6, lines 34-37, and column 7, lines 12-14). Thus, Claims 8-12 and 30 cannot be anticipated by Devlin.

Claims 13-14 describe the path of a scan provided by the scanning means of Claim 1 as being helical. Devlin fails to disclose a helical scan path of its container. Thus, Claims 13 and 14 cannot be anticipated by Devlin.

Claim 16 describes an encoder coupled to the holder of Claim 1. No encoder is disclosed in Devlin for providing signals correlated positionally with a scanning means. Clearly, Claim 16 cannot be anticipated by Devlin.

Claim 17 describes the holder of Claim 1 as a cassette of material substantially free of bi-refringence, and Claim 18 describes that material as being amorphous polyoelefin. Devlin's material specifications at column 5, lines 16-18, neither discloses that its container is of material substantially free of bi-refringence, nor that it is of amorphous polyoelefin material. Therefore, Claims 17 and 18 cannot be anticipated by Devlin.

Claim 23 describes the imaging system of Claim 1 as being operative in accordance with one of optical coherence tomography or two-photon microscopy. Devlin only discloses its imaging as radiological, and thus cannot anticipate imaging by optical coherence tomography or two-photon microscopy. Thus, Devlin fails to disclose each and every element of Claims 2-14, 16-18, 23, and 30, and Applicants request withdrawal of the rejection of these claims.

Claim 19 describes a method for imaging surgical biopsies, and for reasons argued with respect to Claim 1, Claim 19 also cannot be anticipated by Devlin where Devlin fails to disclose any image for pathological examination of the specimen. Claims 20-22 depend on Claim 19. Claim 20 describes the step of making an incision with a trocar

which provides the cassette. No such step is disclosed in Devlin as Devlin shows no trocar for making any incision. Claim 21 describes rotating and translating the cassette with respect to a head of an imaging system to carry out the imaging step of Claim 19. No such rotating or translating of its container is shown in Devlin, as argued earlier in connection with Claims 8-12 and 30. Accordingly, Applicants do not believe that Claims 19-22 are anticipated by Devlin, and request that the rejection of these claims be withdrawn.

Claim 24 describes a system for imaging a tissue sample having means for scanning a cassette to provide at least one image of the tissue sample suitable for pathological examination. For reasons argued with respect to Claim 1, no scanning means is disclosed in Devlin for providing any image of a tissue sample suitable for pathological examination. Claims 25-27 depend on Claim 24. Claim 25 describes means for moving the cassette with respect to the scanning means. No such moving means of its container is shown in Devlin. Claim 26 describes its cassette as of a material optically transparent to the scanning system of Claim 24. However, Devlin's container 16 is not optically transparent since the container has therein "a layer of absorbent material 28 preferably made of paper" (see column 5 at lines 19-21). Paper is typically opaque and thus not optically transparent. Claim 27 describes the scanning means of Claim 24 as being operative by one of confocal microscopy, optical coherence tomography, or two-photon microscopy. None of these imaging modalities is anticipated by radiological imaging. Thus, Claims 24-27 are not anticipated by Devlin, and Applicants request withdrawal of the rejection of these claims.

Claim 28 describes an apparatus for enabling imaging of tissue having a stage which presents the tissue in the cassette to an optical imaging system and means for moving the cassette along a path to enable microscopic imaging of the tissue in the cassette. For reasons argued earlier, Devlin fails to disclose a stage to present the tissue in its container, an optical imaging system, or means for moving its container along a path with respect to the optical imaging system to enable microscopic imaging of tissue. Thus each and every element of Claim 28 is not present in Devlin, and Devlin cannot anticipate this claim.

Claim 29 describes a cassette wherein the chamber may be made of substantially optically transparent material. For reasons argued with respect to Claim 26 the biopsy container is not substantially optically transparent since it includes material, i.e., paper

within the container. Thus, neither Claims 28, nor 29 are anticipated by Devlin, and withdrawal of the rejection of these claims is requested.

New Claims 31-33 are added to the application. These dependent claims describe the image of their respective base claims as representing an optically formed section of the tissue specimen. Radiological images of tissue produced on film are not optically formed images of a section of the tissue, as such radiological images are not even sectional images. Thus Claims 31-33 are patentable over Devlin.

It is believed the application is in condition for allowance. A petition for a one-month extension of time is enclosed with a check for the required petition fee and additional claims fee for new Claims 31-33.

Respectfully submitted,



Kenneth J. LuKacher
Attorney for Applicant(s)
Registration No. 38,539

Dated: August 23, 2004

South Winton Court
3136 Winton Road South, Suite 204
Rochester, New York 14623
Telephone: (585) 424-2670
Facsimile: (585) 424-6196

Enclosures: Combined Transmittal of Amendment and
Petition for Extension of Time with check for \$82.00;
Certificate of Mailing by First Class Mail.